DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0425]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the Federal Register of January 16, 2004 (69 FR 2602). The document announced the proposed collection of information for substances prohibited from use in animal food or feed; animal proteins prohibited in ruminant feed that had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-1062, appearing on page 2602 in the Federal Register of Friday, January 16, 2004, the following correction is made:

1. On page 2602, in the first column, in the heading of the document, "[Docket No. 2002N-0273]", is corrected to read "[Docket No. 2003N-0425]".

Dated: January 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E4-132 Filed 1-27-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E-0037]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUMIGAN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LUMIGAN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product LUMIGAN (bimatoprost). LUMIGAN is indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LUMIGAN (U.S. Patent No. 5,688,819) from Allergan, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 4, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LUMIGAN represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LUMIGAN is 1,967 days. Of this time, 1,787 days occurred during the testing phase of the regulatory review period, while 180 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 29, 1995. The applicant claims October 28, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 29, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: September 18, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for LUMIGAN (NDA 21-275) was initially submitted on September 18, 2000.

3. *The date the application was approved*: March 16, 2001. FDA has verified the applicant's claim that NDA 21-275 was approved on March 16, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 907 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by March 29, 2004. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 26, 2004. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 7, 2004.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E4–130 Filed 1–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Development of Application Guidance for Fiscal Year 2005 Funding Opportunities for New Access Points Under the Consolidated Health Center Program, CFDA Number 93.224

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Solicitation of comments.

SUMMARY: In preparation for the development of Fiscal Year 2005 application guidance for New Access Point funding opportunities under the President's Initiative to Expand Health Centers, the Health Resources and Services Administration (HRSA) is offering public and private nonprofit entities, including tribal, faith-based and community-based organizations, an opportunity to comment on the current Program Information Notice (PIN) 2004–02 titled "Requirements of Fiscal Year 2004 Funding Opportunity for Health Center New Access Point Grant Applications". PIN 2004–02 is available on HRSA's Bureau of Primary Health Care (BPHC) Web site at *http://bphc.hrsa.gov/pinspals/pins.htm*. This PIN details eligibility requirements, review criteria, and awarding factors for applicants seeking support for the operation of a new delivery site for the provision of comprehensive primary and preventive health care services.

HRSA believes that consultation with the community is an integral part of the application guidance development effort directed at creating new and expanded health center access points.

The Opportunity to Comment includes (1) identifying those areas in the guidance that need clarification and/or improvement, and (2) offering suggestions for achieving improvements. Comments will be reviewed, analyzed, and summarized for use in developing requirements for the fiscal year 2005 funding opportunity for health center new access point grant applications.

Background: The goal of the President's Initiative to Expand Health Centers, which began in fiscal year 2002, is to create health care access for 1,200 of the Nation's neediest communities through new and/or significantly expanded health center access points over five years. One way to achieve this goal is through the creation of new access points for the provision of comprehensive primary and preventive health care services in areas of high need that will improve the health status and decrease health disparities of the medically underserved populations to be served. These access points may be targeted toward an entire community or toward a specific population group in a community that has been identified as having unique and significant barriers to affordable and accessible health care services.

Authorizing Legislation: Section 330(e)(1)(A) of the Public Health Service Act, as amended, authorizes support for the operation of public and nonprofit health centers that provide health services to medically underserved populations.

DATES: Please send comments no later than COB March 29, 2004. The comments should be addressed to Dr. Sam Shekar, Associate Administrator for Primary Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, Maryland 20814.

FOR FURTHER INFORMATION CONTACT: Ms. Tonya Bowers, Division of Health Center Development, Bureau of Primary Health Care. Ms. Bowers may be contacted by e-mail at *tbowers@hrsa.gov* or via telephone at area code 301–594–4110.

Dated: January 20, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–1734 Filed 1–27–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

[CBP Decision 04–04]

Recordation of Trade Name: "YOUPAL"

AGENCY: Customs and Border Protection (CBP).

ACTION: Notice of final action.

SUMMARY: This document gives notice that "YOUPAL" has been recorded by CBP as a trade name for Youpal International Inc., an Arkansas corporation organized under the laws of the State of Arkansas, 6900 Cantrell Road, E6, Little Rock, Arkansas 72207.

The application for trade name recordation was properly submitted to CBP and published in the **Federal Register**. As no public comments in opposition to the recordation of this trade name were received by CBP within the 60-day comment period, the trade name is duly recorded with CBP and will remain in force as long as this trade name is used by this corporation, unless other action is required.

EFFECTIVE DATE: January 28, 2004.

FOR FURTHER INFORMATION CONTACT: Gwendolyn Savoy, Paralegal Specialist, Intellectual Property Rights Branch, Office of Regulations and Rulings, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Mint Annex, Washington, DC 20229; (202) 572–8710.

SUPPLEMENTARY INFORMATION: Trade names adopted by business entities may be recorded with Customs and Border Protection (CBP) to afford the particular business entity with increased commercial protection. CBP procedures for recording trade names are provided at § 133.11 *et seq.*, of the Customs Regulations (19 CFR 133.11 *et seq.*). Pursuant to these regulatory procedures, Youpal International Inc., an Arkansas corporation organized under the laws of the State of Arkansas, 6900 Cantrell Road, E6, Little Rock, Arkansas 72207, applied to CBP for protection of its trade name "YOUPAL".

On Monday, October 20, 2003, CBP published a notice of application for the